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FORD, JOHN K	
ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 07/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

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Office Action Summary	Application No. 08/895,936	Applicant(s) Wisniewski
	Examiner FORD	Art Unit 3743

-- Th MAILING DATE of this communication appe rs on th cover she t with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 1-7-02

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) 69-89 is/are pending in the application.

4a) Of the above claim(s) 69-87 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) 88+89 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)

16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .

18)☐ Interview Summary (PTO-413) Paper No(s). _____ .

19)☐ Notice of Informal Patent Application (PTO-152)

20)☐ Other:

Applicants have filed an RCE on 1-7-02 (Paper No. 27), a preliminary amendment on 1-7-02 (Paper No. 28), and a supplemental response on 2-21-02 (Paper No. 29) and a new power of attorney on 2-21-02 (Paper No. 30). Each of Papers 27-29 is treated in turn.

With regard to Paper No. 27, an RCE (unlike a CPA) is a request to continue the prosecution of the currently claimed invention where it left off in the previous action. This case has been through an extensive prosecution already and the Examiner is very reluctant, at the current juncture, to switch to another invention (apparatus claims). Accordingly, method claims 88 and 89 are examined here. See MPEP 819. It is also noted that applicant has already filed numerous divisional cases with apparatus claims in them and can develop any legal theories he wants there. Claims 69-87 are withdrawn as being directed to a non-elected invention.

With regard to Paper No. 28, Applicants have argued that the terms "thermal bridge" and "biophameceutical product" are definite (Paper No. 28, pages 7-9). Applicants have stated that "thermal bridge" (as found in claim 89)is definite and that the Examiner's reading is overly board. The Examiner's broad reading of what constitutes a "thermal bridge" is consistent with the definition this term is given in the specification. See specification page 4, lines 20-24, page 4, line 29-page 5, line 5. On page 15, lines 13-16 the following broad definition is given: "The present invention is useful for both the cooling and heating of a medium. When the medium is frozen the thermal bridges help transfer heat out of the medium. When the medium is being heated the thermal bridges help heat to be transferred into the medium.

The medium can also be a gas being converted to a liquid or a liquid being converted to a gas. In these cases the liquid phase of the medium that collects between the fin and the structure will act as the thermal bridge to enhance conduction of heat between the fin and the structure."

Thus the Examiner's broad reading of a "thermal bridge" is consistent with the broad definition that this term enjoys in the specification. Thus, the term "thermal bridge" is clearly not limited to freezing but also applies to heating situations and, as defined in the specification, and includes an enhancement heat transfer due to geometry (e.g. the closeness of two surfaces) and/or the conductivity of the medium used in the device.

It is noted that claims 88-89 only claim "actively cooling" the annular wall of the vessel. They do not recite freezing of the "biopharmaceutical" and claim 88 does not recite any "active cooling" of the centrally disposed heat exchange structure.

Applicant alleges on page 8 of Paper No. 28, beginning at the middle of the page, that no thermal transfer bridge will form in a device with too large a gap (presumably referring to the 1992 prior art from Basel, Switzerland). The "proof" of this alleged fact is offered in the form of a declaration by one of the inventors (Mr. Wisniewski). With regard to Exhibits B, C and D he states that the temperature distributions shown there "reasonably resemble" the actual temperature profile, "to the best of his knowledge".

There is no evidence that these are actual measured results (the best form of proof in this particular case) or are even computer generated results. No disclosure is given for the materials and sizes of the components depicted. No disclosure of the gap size is given in Mr. Wisniewski's

analysis. No disclosure is given for how Mr. Wisniewski determined these curves. No calculations are shown. No factual supporting materials are given to support that Mr. Wisniewski's estimates or guesses at the temperature profiles are in fact reflective of reality. The proof as it stands is not convincing.

Particularly unconvincing in the Examiner's mind is Exhibit D, where ice has clearly bridged the distal end of the heat transfer fin and the inner side of the annular cooled wall.

At that point, Fourier's law of heat conduction essentially begins to take over, and the temperature profile as time goes on will begin to have a linearly downward slope determined by the difference in temperature between the distal end of the fin and the inner side of the annular wall.

It is noted for the record, that Figure 3b of the specification depicts the temperature profile at some undisclosed time after cooling has been occurring. It does not show the temperature profile at a time immediately after cooling has been initiated. It is submitted that immediately after cooling is initiated, for the geometry shown in Figure 3b of the specification, the characteristic "peak-shaped" temperature profile depicted in Exhibits B and C will apply to Applicant's device, because of self-evident principles of heat transfer.

As stated by the Examiner in Paper No. 25, there is really no difference in the fundamental heat transfer physics which occurs in applicant's device of Figure 3B and that depicted in the 1992 publication.

The bridging will admittedly occur more quickly in a small gap than in a large gap, but the temperature profile once enough material is frozen in and around the gap will have a linear profile whose slope is entirely determined by the relative temperatures at the end of the fin and the inside of the wall.

Moreover this Examiner who holds a masters degree in Engineering from Princeton University, does not believe that there is anyone who can model or calculate these temperature profiles without the aid of Sophisticated computers and/or experimental work. On this point see Kalhori & Ramadhyani "Studies on Heat Transfer From a Vertical Cylinder, With or Without Fins, Embedded in a Solid Phase Change Medium", page 44, second and third paragraphs. The processes of modeling natural convection and moving-front phase change occurring together with sub-cooling is, to the Examiner's knowledge, is state of the art or beyond the state of the art in numerical solutions on computers. If applicants know otherwise please submit appropriate proof.

The definition of "biophamaceutical product" offered by Burman, Lawlis, Jr. and Vetterlein is fine as far as it goes but it appears to <u>conflict</u> with the one offered in the specification because some of the examples given in the specification, most notably "buffer solutions" do not fit the definition offered up by Burnam, Lawlis, Jr. and Vetterlein. On this last point, applicant argues that "blood or other body fluids" are buffer solutions and "are indeed biopharmaceutical products due to mixtures of weak acids and bases present in them" (remarks, sentence bridging pages 11 and 12). The argument is unconvincing. The Examiner has never heard of "blood" being a known as a buffer solution. Buffer solutions, it is respectfully submitted, are known in the

art to be weak acids or bases of known pH used in chemical laboratories. If blood was a known "buffer" why is it (along with "plasma") given as a separate example of a "biopharmaceutical product" in the list found on page 7, lines 4-9?

In response to this action please submit factual materials to support the assertion that "blood" is known to those of ordinary skill to be an example of a "buffer solution".

Counsel maintained that the 1996 DMT article was less than a year old and was the inventors' own work and thus did not constitute prior art under any section of 35 USC 102 and hence under 103. The Examiner then required a copy of the 1992 article which clearly constitutes prior art under 102(b) and is materially more detailed as to the structure of the heat transfer system that then 1996 DMT article. In response to that request applicant (in SN 08/895,782) sent yet another 1996 article (published by Advanstar) however on the first page of the text of that article (see footnote at bottom) it is disclosed that the Advanstar article was previously published in February of 1992.

The Examiner also needs and exact publication date (month and day) for each of the 1996 articles (Advanstar, and the Drug Manufacturing Technology Series, Vol. 2) to ascertain their prior art status as to this application. It is noted that both 1996 publications have authorship which <u>differs</u> from the current inventive entity and hence would be prior art under 102(a) and the case law interpreting "another". If counsel continues to insist the 1996 publications are not prior art, please address in detail his reasons why they are not. Please address some comments of the

differing inventive entity vis-a-vis the authorship entity, and why they should not be treated as disparate under 35 USC 102(a).

On pages 2 and 3 of the specification under a section entitled "Description of the Prior Art" applicants appear to disclose that liquids, possibly biopharmaceuticals, have been heated and cooled in containers which have structures comprising "extensions of the container or any structures in the container". Fins are mentioned specifically but are "typically attached to the container or an internal structure at only one point".

Full disclosure of this prior art is needed. If applicant does not have a publication, a carefully drawn sketch with meaningful legends and explanations is required. Disclosure of what processes (e.g. heating, cooling, freezing etc.) have been performed in this acknowledged prior art described on pages 2 and 3 of the specification is required as well as what fluids (e.g. biopharmaceuticals etc.) have bee processed in the acknowledged prior art container.

Moreover the 1992 disclosure of Wisniewski and Wu doe snot disclose how close to the wall of the container the heat transfer fins extended, the dimensions of those fins (length, width, height and thickness), the diameter of the container and the volume of the container. Because applicants are in possession of this information and the examiner has no other reasonable way to obtain it, a requirement under Rule 1.56 and Rule 1.105 is set forth here. Timely submission of this information will permit an orderly examination and will avoid the Board having to require such information under Rule 1.196(d) should an appear be forthcoming. Applicant must known this information because he apparently used it to generate Exhibits B, C and D.

Claims 88 and 89 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out distinctly claim the subject matter which applicant regards as the invention.

The term "thermal bridge" as used in claim 88 of this application is vague. It appears to denote any area where one thermally conditioned surface is in greater proximity to another surface (either itself thermally conditioned or unconditioned) than it is to other surfaces within the device. Is that a correct understanding? If not, why not? If not, what is it? It is submitted that the entire content of fluid in the tank will conduct heat, and that any conditioned structure within the container will conduit heat out of the medium if it is cooler than the medium. The opposite is true for a heated surface.

The term "biopharmaceutical product" as it is used in this application is ambiguous and hence its use in claim 88 is also the source of ambiguity. In <u>contrast</u> with what may be accepted "biophrmaceutical products" such as a product derived from biological sources that has an intended therapeutic application and whose manufacturing is or will be regulated by pharmaceutical or veterinary regulator agencies (see "132 declarations in Paper No. 17), in the specification applicants state that the present invention can be used to "freeze and preserve a variety of biopharmaceutical products, including but not limited to proteins, cells, antibodies, medicines, plasma, blood, buffer solutions, viruses, serum, cell fragments, cellular components, and any other biophrmaceutical product".

Many of the purported biopharmaceuticals on applicants' list in the specification are not normally considered biopharmaceuticals on applicants' definition (offered up in the '132 declarations in Paper No. 17) above. For example, buffer solutions are acids or bases-dissolved in water not derived from biological sources nor regulated by FDA to the Examiner's knowledge. Blood, per se, such as is drawn from the general population by the Red Cross would not appear to be a biopharmaceutical by affiant' definition yet it appear on applicants' list. On page 133, col. 1, fourth full paragraph, of the 1992 Wisniewski and Wu prior art (Paper No. 20), it states that "buffer salts" can be components of a biphharmaceutical product but it appears the "buffer salts" are not themselves a biopharmaceutical product. "Medicines" are simply understood to be drugs or other agents used to treat disease or injury. They need not be derived from biological sources. What is vital to this examination is to know with reasonable particularity what chemicals when placed in applicants' tank would infringe the claims. Under applicants' expansive definition of biopharmaceuticals int he specification it would appear that many conventional organic and inorganic solutions (e.g. buffer solutions) would be included-against what affiant Arathoon, Burman, Lawlis and Vetterlein (Paper No. 17) would consider to be the reasonable limits of the word. On the other hand, orange juice recently shown to have measurable effects against certain forms of cancer, was suggested by counsel to not seriously be considered a biophrmaceutical. The Examiner disagrees. If buffer solutions are considered to be biopharmaceuticals and blood, per se, drawn from the general populations biopharmaceutical, it doesn't seem reasonable to exclude orange juice. The chances of the FDA regulating "buffer solutions" as pharmaceutical in

the future would be about on par with the chances of the FDA regulating orange juice as a biopharmaceutical in the Examiner's opinion. If the definition now includes orange juice based on new research showings its anticancer properties and possible future regulation by the FDA then applicants' use of the word biophrmaceutical seems to include an ever growing and somewhat amorphous list of chemicals what would be perpetually changing as new research was done to show therapeutic properties to products produced by biological processes such as photosynthesis, fermentation and biological agents such as herbs, roots and compounds which are essentially the products of nature. It is impossible to know which of these will be regulated by the FDA in the further given the vicissitudes of government regulation. The term as it is used in the application is deemed by the Examiner to be one that violates the tenets of 35 USC 112 in that the metes and bounds of the claims cannot be established with the requisite clarity required by the statute and are subject to change based on further FDA actions. The would-be infringer would have no clear way to determining infringing behavior, to put it another way. Infringement would be constantly changing depending on what the FDA decided to regulate as a biopharmaceutical. It is noted that the FDA regulates the handling and composition many food items, but that doesn't transform them into biopharmaceuticals even if those food items have some therapeutic benefit. The definition offered by the declarants appears to be unworkable in the Examiner's opinion and that offered in the specification ambiguous.

The declarations under Rule '132 by Arathoon, Burman, Lawlis and Vetterlein (see Paper No. 17) all appear to define "biopharmaceutical products" much more narrowly than the

expansive definition given in the specification. For example, the Examiner knows of no biologically sourced "buffer solution" which in and of itself is regulated by the FDA. Moreover, it there were such a solution, why would it freeze any differently than a buffer solution not regulated by the FDA nor biologically sourced? It is noted that there is a tremendous variety of "biopharmaceutical products" in applicant's list some of which are very large: cells (e.g. blood etc.) whereas others are millions if not billions of times smaller (e.g. viruses or salt ions in a buffer solution). It is submitted that the freezing characteristics of solutions at these two extremes would be extremely different. Blood would probably freeze more in the manner of orange juice or milk given its nearly macroscopic cellular nature whereas virus in a suitable buffer solution or water would freeze in the manner of pure or salty water. Affiant Arathoon, Burman, Lawlis and Vetterlein all state in their conclusions that Cothern, Nakamura and Morrison (disclosing orange juice, solid particles in a liquid carrier and milk, respectively) do not suggest or teach devices or methods useful in processing biopharmaceutical products. Lacking in any of the declarations is any supporting reasons or analysis to show why declarant Arathoon, Burman, Lawlis and Vetterlein hold this opinion common to all of them. None of the affiant have provided any facts to support such a sweeping conclusion. Moreover Applicants' response as well as the declarations under Rule '132 have failed to reconcile the definition of "biophrmaceutical products" stated in the declarations with the disclosure of the chemicals and blood products, medicines, buffers etc. offered up as examples of "biophrmaceutical products clearly encompasses more chemicals than Affiant' declarations under Rule '132. To the extent that the Rule '132

declarations define the term "biophrmaceutical product" more narrowly than what is disclosed in the specification, the declarations serve to heighten the ambiguity of the disclosed and claimed "biopharmaceutical products" and what the limits (metes and bounds) of that terminology is to have as claim limitation. Moreover, in regard to the cited prior art, nothing in the declarations has addressed why one designing freezing equipment for the chemicals disclosed in the specification would not look to the art of freezing water, orange juice or solids suspended in liquids. The declarations under 37 CFR 1.132 (Paper No. 17) are not convincing for these reasons.

PRIOR ART REJECTIONS

Claims 88 and 89 are rejected under 35 USC 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the 1992 publication by Wisniewski and Wu.

The 1992 Wisniewski and Wu research paper appears to disclose every feature of the claimed invention including heat exchange members (i.e. fins) in close spaced proximity to the interior surface of the container. To the extent that the distance between the tip of the fin and the wall of the container is quantified by the phase "in close spaced proximity", the reference appears to answer to the limitation. See Figure 1 and the description thereof found on pages 134 and 136. Note page 135 should follow page 136 and was apparently printed out of order. The Examiner did not catch this error when he examined SN 08/895,782.

There is no explicit disclosure of any ice bridge in the 1992 Wisniewski and Wu research paper (if that what is being claimed in the phrase "thermal transfer bridge", however see specification, page 5, lines 10-13, for apparently inconsistent definition: when the medium is being

heated, after being frozen, the ice in the "gap" claimed between the tips of the fins and the wall of the container melts quickest leaving liquid in that "gap", hence it would appear that "thermal transfer bridge" is a much broader term than simply an ice bridge) formed between the tips of these fins and the interior wall of the container and no explicit disclosure of how close to the container wall these heat transfer fins extend, although they much extend far enough to define "compartments" between the fins (1992 Wisniewski and Wu research paper, page 136, first full paragraph).

The thermal bridge of ice will inherently form between the tip of the heat transfer fins and the interior of the container because they are the closest points to one another and both are actively cooled by circulating cooled silicon oil. Closely spaced cooled surfaces are known by those of skill in the refrigeration art to form ice bridges when a liquid is being frozen into a solid.

As evidence to support the Examiner's statement the closely spaced cooled surfaces will inherently form ice bridges (see MPEP 2112-2112.02, dealing with inherency, incorporated here by reference), the reader is referred to Voorhees USP 983,466, page 1, col. 2, line 97-page 2, col. 1, line 5 (Voorhees is not relied upon explicitly here, see MPEP 2131.01, sub-section III), wherein it states:

"Whether ice forms in single cakes about several freezing elements or forms in a single cake inclosing a plurality of such elements depends upon the spacing of the several freezing elements from each other. In the first instance of course, ice forms separately about each freezing element, but if these elements be ***close together*** the ice surrounding these elements will soon

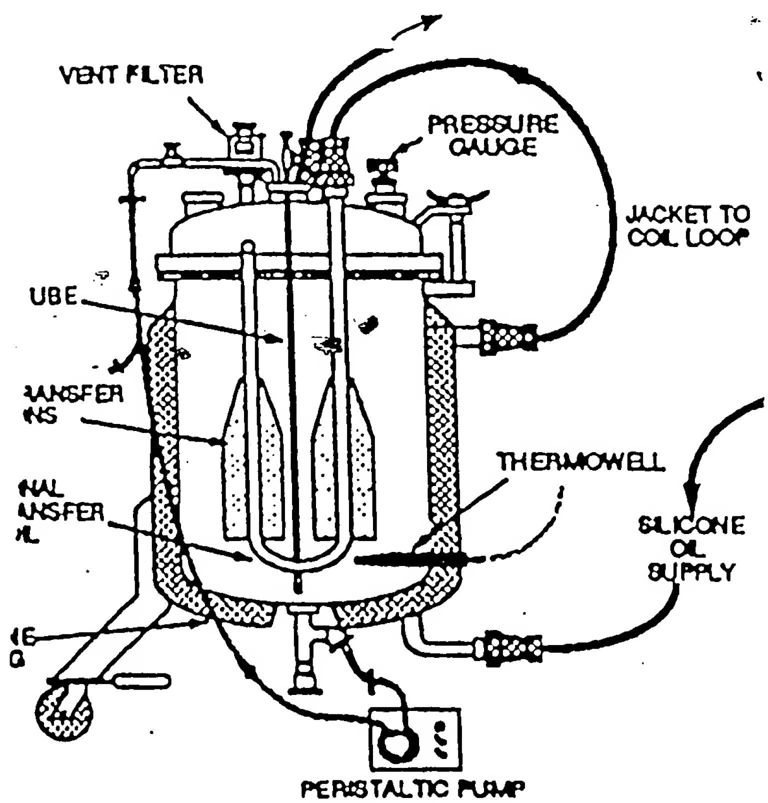
coalesce into a single cake; and after this has occurred freezing will go on from the surface of the combination cake so formed." (Emphasis supplied).

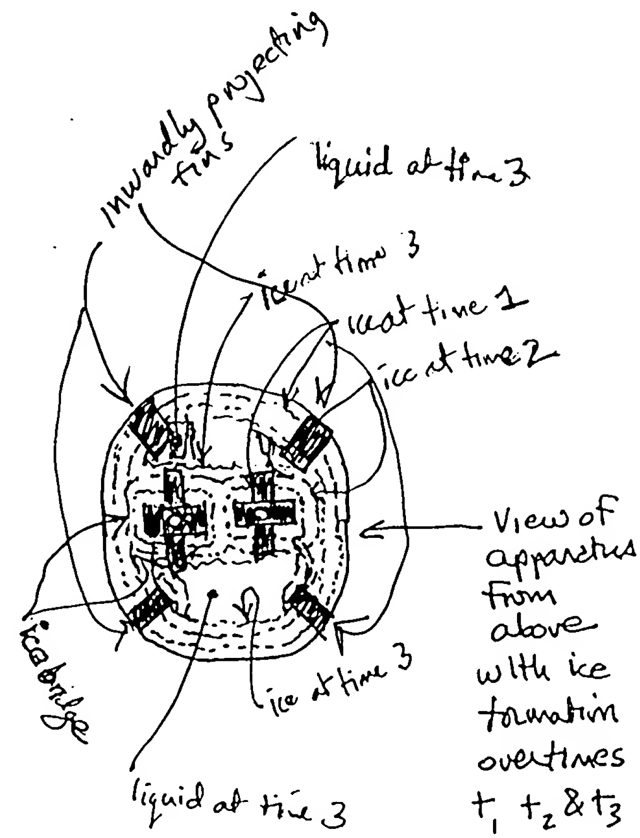
Furthermore, Voorhees, page 2, col. 1, lines 14-21 states:

"I have shown a number of other elements so spaced relatively as to form a single cake 15 of length comparable to cakes formed in plate processes. Of course if the ***freez-ing wee continued indefinitely the cakes 12, 13, 14 and 15 would eventually coalesce and freeze to the sides of the tank...***"

It is evident that ice will build up on the heat exchanger and walls of the vessel shown in Figure 1 of 1992 Wisniewski and Wu research paper, during the freezing phase, until they bridge as shown in the diagrams below, a fact that can be established by basic scientific principles. Burroughs et al. USP 3,318,105 illustrates the phenomena. As is clearly seen in Figs. 1A-1C ice builds up evenly on cooled surfaces and even as the top surface freezes the ice coating on the submerged surfaces continues to build up more or less evenly. The same type of analysis is disclosed by Finnegan USP 2,129,572, illustrating that the time required to freeze a substance varies "approximately as the square of the thickness of such substance" with slower freezing generally leading to undesirable concentration effects (what applicants and the 1992 Wisniewski and Wu research paper refer to as "cryoconcentration"). Finnegan, like the 1992 Wisniewski and Wu research paper, discloses the use of heat exchanges fins (projecting inwardly from the exterior wall of the container in the case of Finnegan) to form compartments within the tank to speed the freezing process. Finnegan illustrates using a series of dotted lines how the freezing process

progresses over time in various geometries of heat exchange fins. Applying this same science (illustrated by Burroughs and Finnegan) to the system disclosed by 1992 Wisniewski and Wu research paper yield the results illustrated on next page for the system disclosed by the 1992 Wisniewski and Wu research paper in Figure 1.





Even if the 1992 Wisniewski and Wu research paper is deemed not to disclose heat exchanger fins “in close spaced proximity” to the container wall, to have extended the fins in Figure 1 of the 1992 Wisniewski and Wu publication to a point “in close spaced proximity” to the

interior surface of the container in order to advantageously increase the rate of heat transfer and "divide the tank volume into compartments to decrease the freezing and thawing time and to reduce cryoconcentration effects" (1992 publication, page 136, col. 1, first full paragraph) would have been obvious to one of ordinary skill in the art.

The examiner submits that the fins in Figure 1 of the 1992 Wisniewski and Wu publication are already in spaced proximity to the interior wall of the container such that substantially discrete compartments are formed (see page 136, col. 1, first full paragraph) an effect that would be enhanced if the fins were further extended to a point closer to the interior wall of the container.

Moreover, larger fins would increase the amount of surface area for heat transfer, giving an added advantage. On page 136 of the 1992 Wisniewski and Wu publication it states that the "fin's length, thickness and shape were designed to maintain ***efficient heat transfer*** during freezing and thawing." (Emphasis supplied). It is not open to any serious debate that larger, thicker, fins that extend to points closer to the interior wall of the container are more efficient heat transfer, vehicles than smaller, thinner fins that do not extend to points closer to the interior wall of the container.

The 1992 Wisniewski and Wu publication states on page 136: "The heat transfer fins were configured to divide the tank into compartments to decrease the freezing and thawing time and to reduce cryoconcentration effects. Compartmentation of the tank is especially effective for maintaining liquid in a static state to minimize cryoconcentration". (Emphasis supplied). The fins are designed to maintain "efficient heat transfer during freezing and thawing" (a page 134, col. 2,

1992 Wisniewski and Wu publication). Figure 1 (page 134) of the 1992 Wisniewski and Wu publication clearly shows heat transfer fins extending outwardly from the internal heat transfer coil towards the interior wall of the container. Extending the fins further outwardly to aid in the formation of compartments to minimize cryoconcentration would have been another motivation to one of ordinary skill in the art to make the same modification.

Claims 88 and 89 are rejected under 35 USC 103(a) as obvious over the 1992 publication by Wisniewski and Wu as applied to claims 88 and 89 above and further in view of: Euwema (USP 3,550,393), Cothern et al. (USPN 5,535,598), the 1986 Kalhori and Ramadhyani article entitled "studies on heat transfer from a vertical cylinder, with or without fins, embedded in a solid phase change medium" (reference 29, on page 140 of the 1992 article by Wisniewski and Wu), Morrison and Nakao.

Euwema discloses ice bridges forming at the ends of vanes 36 and 38 when wall 10 is cooled by a refrigerant. See column 3, lines 4-19. The ice is shown at 18 (Figure 1) and rapidly bridges the gap between the tips of vanes 36 and 38 and the cooled surface 10 of the refrigeration device (Figure 2) in much the same manner that applicants disclose in their specification with regard to ice forming in the gap between the tips of their fins 8 and the inner wall of their container. Euwema's ice divides the regions on either side of vanes 36 and 38 into separate compartments to facilitate improved heat exchange with the liquid in those compartments. In other words, the ice bridges in Euwema prevent the fluids in the compartments on either side of vanes 36 and 38 from intermixing in much the same manner that the 1992 publication by

Wisniewski and Wu discusses is a desirable feature in their invention (see the 1992 publication by Wisniewski and Wu, page 136, first full paragraph- "The heat transfer fins were configured to divide the tank volume into compartments to decrease the freezing and thawing time and to reduce cryoconcentration effects").

Likewise, Cothern et al teaches (Figures 1-3) a jacketed tank (Figure 2) similar to applicants and a fin-like heat exchanger formed with plates that divide the interior of the tank into a number of compartments by spanning nearly the entire tank to areas very close (close spaced gaps) to the sidewalls of the tank (in much the same manner applicants disclose, albeit in a square tank as opposed to a round tank). These large heat exchanger plages provide great surface area for improved freezing as discussed by Cothern in column 7, lines 46-52. In Cothern, having these closely spaced gaps between the distal ends of the immersed heat exchanger and the walls of the jacketed tank permits the heat exchanger to be withdrawn easily for cleaning and reduces the need for tight manufacturing tolerances in the immersed heat exchanger such as might be encountered in trying to make the immersed heat exchanger fit tightly into the tank and form fully non-communicating compartments.

The 1986 Kalhori and Ramadhyani article "Studies on heat transfer from a vertical cylinder, with or without fins, embedded in a solid phase change medium" (reference 29, on page 140 of the 1992 article by Wisniewski and Wu), like applicants have disclosed in Figures 1 & 2 of their drawings, shows in Figure 3 a "spur-tube" type heat exchanger with six heat transfer fins welded to it in a manner almost identical to what applicants show in Figures 1 and 2 of the current

application. The finned heat exchanger as shown in immersed in a container of paraffin and the melting and freezing processes were studied in great detail with a material, paraffin, or known characteristics. See the abstract of this article on the first page. Again, fins that span nearly the entire interior of the container were found to be especially effective, with a host of definitive technical data presented (that is unnecessary to discuss here) showing the virtues of these large fins improving heat exchange. See last sentence of article- "In view of the ***superior heat transfer characteristics, the finned cylinder*** is a much better choice for the design of a practical thermal storage unit." (Emphasis supplied).

Morrison also teaches that fins 7 spanning nearly the entire interior of a container (which container is believed to be shown in phantom lines in Figure 1) 'insure maximum heating or cooling surface, so that operation of the device may be carried out with facility" (Morrison, column 1, lines 8-13).

Finally, Nakao teaches metallic fins 5 spanning nearly the entire interior of a container having a phase-change material therein. A relatively small gap exists between the end of these fins and the wall of the container. These fins greatly aid in the transfer of heat introduced at, and removed from, the periphery of the container.

In view of each of the above teachings, it would have been obvious to one of ordinary skill in the art to have extended the fins of the prior art disclosed in the 1992 article by Wisniewski and Wu to substantially the inner periphery of the container, leaving a small gap to permit the heat exchanger to be removed for cleaning (as is disclosed to be necessary in the 1992 article by

Wisniewski and Wu on page 136). Extended the fins to substantially the inner periphery of the container would:

a. Improve heat transfer by increasing heat transfer surface area as taught by Cothern, Kalhori & Ramadhyani, Morrison, Nakao and

b. Improve "commpartmentation" by forming ice bridges as explicitly taught by Euwema.

Claims 88 and 89 are rejected under 35 USC 103(a) as being unpatentable over any of the prior art as applied to claim 88 and 89 and further in view of Cothern (USP 5,535,598).

Cothern in column 7, line 54-column 8, line 8 teaches various controls for controlling both rate and cooling direction in a freeze container by varying refrigerant flow in the various portions of the device. To the extent that the system disclosed by applicants in Figures 1 & 2 can accomplish the functions set forth in claims 76, 77 and 79, it would have been obvious to have configured the 1992 Wisniewski and Wu prior art with suitable controls to achieve the same end (those controls being broadly taught by Cothern). Since applicants' own specification is virtually devoid of how these functions are accomplished it must be surmised that obtaining these results must be within the skill of those skilled in the refrigeration art.

Any inquiry concerning this communication should be directed to John Ford at telephone number 308-2636.

John K. Ford
Primary Examiner

J. Ford

June 2, 2002